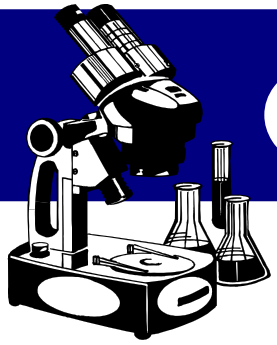

# CLIA BITS

North Dakota Department of Health
Division of Health Facilities Spring 2004

## Calibration and Calibration Verification for Nonwaived Testing

Effective April 24, 2003, calibration and calibration verification procedures now apply to all nonwaived tests. These procedures are required to substantiate the continued accuracy of the test system throughout the reportable range for the test system. The calibration and calibration verification requirements are found at 42 CFR 493.1255. So what is required by the new CLIA regulations for calibration and calibration verification?

### CALIBRATION

Calibration is the process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

A laboratory must perform calibration following the manufacturer's instructions using calibration materials provided or specified and with at least the frequency recommended by the manufacturer. The test system's instructions should specify the process for performing calibration, including the frequency, number, type and concentration of the calibration material. The laboratory must also calibrate whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

All calibration activity must be documented and retained for two years.

Calibration is not required for:

- Manual procedures not involving an instrument such as microbiology cultures, Kirby -Bauer disk susceptibility tests, tilt-tube prothrombin time test systems, ABO and D(Rho) typing.

- Microscopic procedures such as KOH preparations, pinworm preparations, urine sediment analysis, all manual differential procedures and manual cytology screening procedures.

- Procedures involving an instrument in which calibration is not practical such as prothrombin procedures.

**Inside this issue:**



**Special points of interest:**

- Calibration and calibration verification apply to moderate and high complexity tests.
- Use your laboratory's information system to assist in record retention.

*Calibration and Calibration Verification* (cont)

## CALIBRATION VERIFICATION

Calibration verification is the assaying of materials of known concentration in the same manner as patient specimens to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

A laboratory must perform calibration verification procedures at least once every six months or more frequently if required by the manufacturer. Calibration verification must also be performed whenever:

- A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results and control values are not adversely affected by reagent lot number changes.
- There is major preventive maintenance or replacement of critical parts that may influence test performance.
- Control materials reflect an unusual trend or shift or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
- The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Calibration materials, proficiency testing samples with known results, or control materials with known values may be used to perform calibration verification. For these materials, the laboratory must define acceptable limits for the difference between the measured values obtained versus the actual concentration of the materials. The material should include at least a low, mid and high value to verify the laboratory's reportable range.

All calibration verification activity must be documented and retained for two years.

The calibration verification requirements are met:

- If the laboratory performs a calibration protocol using three or more levels of calibration materials that include a low, mid and high value at least every six months.
- For kinetic enzymes by verifying the procedure using a high enzyme level material such as a control, calibration material or patient specimen and diluting it to cover the reportable range.

Calibration verification is not required:

- For automated cell counters if the laboratory follows the manufacturer's instructions for instrument operation and tests two levels of control materials each day of testing, provided the control results meet the laboratory's criteria for acceptability.

- If the laboratory follows the manufacturer's instructions for instrument operation and routinely tests three levels of control materials (lowest level available, mid-level and highest level available) more than once each day of testing, the control material results meet the laboratory's criteria for acceptability and the control materials are traceable to National Institute of Standards and Technology (NIST) reference materials.

For more information and a CLIA brochure relating to calibration and calibration verification, go to www.cms.hhs.gov/clia/default.

# CLIA Record Retention

The CLIA regulations require that all instrument printouts be kept for at least two years. How does this apply to interfaced systems where the reports can be accessed through the laboratory information system (LIS)?

For data transferred by computer interface, it is not necessary to retain paper worksheets or printouts if the computer retains the data for at least two years. Manual entry of patient result data requires that all worksheets and printouts be retained by the laboratory for at least two years. If the results are entered via download or direct interface to the LIS, the instrument printouts need not be saved. If, however, results are transcribed from instrument printouts into the computer or into the patient report, the printouts need to be retained for two years. In the event that the interface is down and the results are manually entered, a hard copy or original must be kept in case there is a question about the transcription. The original result report must be retained for two years in hard copy or in the computer if it can be retrieved and reprinted.

It is the simple things in life that make living worthwhile, the sweet fundamental things such as love and duty, work and rest, and living close to nature.

Laura Ingalls Wilder

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